

REMARKS

This is in response to the Office Action dated October 31, 2008. Claims 20, 22-24, 26, 27, 30-34, and 37-38 are rejected. Claim 35 is withdrawn. Claim 36 is objected to. Claims 20, 22, 34, and 36 have been amended. Support for the amendments can be found throughout the specification and the Figures, and at least on page 8, lines 3-9, page 14, lines 19-22, and page 21, lines 10-19. Reconsideration and allowance of the claims are requested.

Claims 20, 22-24, 26-27, 30-34, and 37-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (5,449,384) in view of Williamson IV et al (6,402,780).

The Office Action states that Johnson discloses a method for attaching a porcine heart valve prosthesis comprising inserting fasteners 708, 710, 712 (sutures) through the prosthesis and through an aortic wall 700 (fig. 17). The Office Action states that the prosthesis comprises leaflets 724, 726, 728 with commissure supports 210, 212, 214 and reinforcements 220, 222, 218 positioned along an inner surface of at least one of the commissure supports. The Office Action states that the reinforcements 220, 222, 218 are unitary pledges or suture pads, wrapped around the commissure supports.

The Office Action states that the reinforcements include an aperture (Fig. 3), and that the fastener is inserted through the aperture and into the aortic wall (See fig. 17). The Office Action states that it would have been obvious to employ the suturing method including pledges as disclosed by Johnson with a stentless prosthetic valve (for example Quintero, 5,197,979), since such modification would have been a combination of prior art elements yielding predictable results.

The Office Action states that Johnson fails to show fastener having a head and sharp barbed tip, but that Williamson IV et al teaches the use of a fastener having a head and sharp barbed tip (e.g. Fig. 65).

Claim 20, as amended, recites that the reinforcement comprises a first leg and a second leg connected together with a top portion, and that the reinforcement is positioned along an inner surface of at least one of the commissure supports, wherein an end of the first leg extends to a first scallop and the end of the second leg extends to a second scallop, and wherein

the reinforcement is configured to be positioned proximate a curved outflow edge of the at least one commissure support. Claims 22 and 34 have similar limitations.

In contrast, Johnson discloses a framework 200 having three struts, each strut ending in a pad 218, 220, 222. Pads 218, 220, 222 are considered as the reinforcements by the Office Action. However, the reinforcements are not configured to be positioned proximate a curved outflow edge of the prosthesis, as claimed. Williamson does not cure the deficiencies of Johnson.

Further, valve leaflets of Johnson are mounted to the framework 200 such that the aortic wall tissue associated with the edge of each leaflet is wrapped around the struts. Tabs are folded over what the Office Action calls reinforcements at the ends of the struts. The resulting structure is a valve that is entirely covered with porcine heart tissue. See column 4, lines 54-64. The reinforcements are entirely covered by the porcine tissue, and thus, are not positioned along an inner or outer surface of the prosthesis, as claimed. Williamson does not cure the deficiencies of Johnson.

There is no disclosure in Johnson of utilizing reinforcements 218, 220, 222 which have legs that connect together with a top portion. In addition, reinforcements 218, 220, 222 do not have legs that extend to a scallop of the prosthesis, as claimed. Williamson does not cure the deficiencies of Johnson.

Reinforcements are particularly advantageous in the implantation of stentless valves, and are used to simplify the deployment of fasteners and stabilization of the deployed fasteners. A physician can reduce the time to implant the prosthesis and the complexity of the implant procedure. See page 7, lines 11-27.

Johnson discloses a stented heart valve that has an internal framework, or stent. The stent in Johnson aids in the implantation of the valve. Stents obviate the need for reinforcements. A stent design can be modified to achieve the desired internal structure for a heart valve. Since Johnson utilizes a stent, there is no need for additional reinforcements.

The combination of Johnson and Williamson does not teach, suggest or render obvious the claimed method. For at least the above reasons, Applicant respectfully requests

withdrawal of the rejection of claims 20, 22-24, 26, 27, 30-34, and 37-38 as being unpatentable over Johnson in View of Williamson IV.

In view of the foregoing, it is submitted that the application is in condition for allowance. The Examiner is requested to contact the undersigned representative if the Examiner believes it would be useful to advance prosecution.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

WESTMAN, CHAMPLIN & KELLY, P.A.

By: Hallie A. Finucane
Hallie A. Finucane, Reg. No. 33,172
900 Second Avenue South, Suite 1400
Minneapolis, Minnesota 55402-3319
Phone: (612) 334-3222 Fax: (612) 334-3312

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